IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ICU MEDICAL, INC., Plaintiff, v. RYMED TECHNOLOGIES, INC., Defendant.	)	C.A. No. 07-468-JJF **JURY TRIAL DEMANDED**

DECLARATION OF KATHERINE NOLAN-STEVAUX IN SUPPORT OF ICU'S OPPOSITION TO RYMED'S MOTION TO TRANSFER VENUE

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Dated: October 29, 2007
828257 / 32116

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ICU MEDICAL, INC., Plaintiff, v. RYMED TECHNOLOGIES, INC., Defendant.	)	Civil Action No. 07-468-JJF

DECLARATION OF KATHERINE NOLAN-STEVAUX IN SUPPORT OF ICU'S OPPOSITION TO RYMED'S MOTION TO TRANSFER VENUE

I, Katherine Nolan-Stevaux, declare and state as follows:

I am attorney in the law firm of Morrison & Foerster LLP, counsel of record for Plaintiff ICU Medical, Inc. ("ICU") in the above-referenced matter. I have personal knowledge of all the facts contained herein and, if called to testify, could and would competently testify thereto.

1. I am informed that on October 24, 2007 ICU filed a Notice of Appeal from the final judgment in the *ICU Medical v. Alaris Medical Systems* litigation in the Central District of California.

2. On September 21, 2007, Judge Mariana R. Pfaelzer, of the Central District of California, entered final judgment in *ICU Medical, Inc. v. Alaris Medical Systems, Inc.*, Case No. 8:04-cv-00689. On October 19, 2007, Judge Pfaelzer issued two orders in *Medegen MMS, Inc. v. ICU Medical, Inc.*, Case No. 06-619 case. The first order dismissed ICU's

counterclaims without prejudice. The second order was a final judgment that ICU's CLC2000 did not infringe any claim of Medegen's asserted patent. Attached hereto as Exhibits A and B are Judge Pfaelzer's Orders dated October 19, 2007.

3. To the best of my knowledge, Dave Arnold has never testified in any intellectual property litigation involving ICU. In contrast, ICU's lead patent attorney at Knobbe Martens Olson & Bear LLP has been deposed multiple times and was prepared to testify at trial in the Northern District of California in the *ICU Medical, Inc. v. B. Braun* litigation (C-01-320. I know of no reason why any of ICU's patent attorneys who may be properly called as witnesses in this case cannot testify either by deposition or if necessary at trial.

4. Dr. George A. Lopez is the inventor of the patents-in-suit and is currently the Chairman of the Board of ICU, as well as its President and Chief Executive Officer. He is prepared to appear to testify in this action by deposition or at trial if necessary.

5. The following counties are included within the Northern District of California federal judicial district: Alameda, Contra Costa, Del Norte, Humboldt, Lake, Marin, Mendocino, Monterey, Napa, San Benito, San Francisco, San Mateo, Santa Clara, Santa Cruz, and Sonoma.

6. The following counties are included with the Eastern District of California federal judicial district: Alpine, Amador, Butte, Calaveras, Colusa, El Dorado, Fresno, Glenn, Inyo, Kern, Kings, Lassen, Madera, Mariposa, Merced, Modoc, Mono, Nevada, Placer, Plumas, Sacramento, San Joaquin, Shasta, Sierra, Siskiyou, Solano, Stanislaus, Sutter, Tehama, Trinity, Tulare, Tuolumne, Yolo, and Yuba.

7. The following counties are included within the Central District of California federal judicial district: Los Angeles, Orange, Riverside, San Bernardino, San Luis Obispo, Santa Barbara, and Ventura.

8. Modesto is in Stanislaus County in the Eastern District; San Jose is in Santa Clara County in the Northern District; Burlingame is in San Mateo County in the Northern District; San Francisco is in San Francisco County in the Northern District; Paradise is in Butte County in the Eastern District, and Roseville is in Placer County in the Eastern District.

9. Attached hereto as Exhibit C is a true and correct copy of RyMed's contact information as listed on its website at http://www.rymedtech.com/html/contact.htm.

10. Attached hereto as Exhibit D are true and correct copies of Google Map directions from Franklin, Tennessee to Wilmington, Delaware and to Los Angeles, California.

11. Attached hereto as Exhibit E is a true and correct copy of Judge Breyer's November 8, 2004 Claim Construction order in *ICU Medical Inc. v. B. Braun Medical, Inc.*, Case No. 01-3202, construing terms of U.S. Patent No. 6,669,673.

12. Attached hereto as Exhibit F is a true and correct copy of Judge Breyer's March 14, 2005 Order granting in part ICU's motion for summary judgment of infringement in *ICU Medical Inc. v. B. Braun Medical, Inc.*, Case No. 01-3202.

13. Attached hereto as Exhibit G is a true and correct copy of excerpts from the LegalMetric District Judge Report for the Central District of California, covering Patent cases from January, 1991 to April, 2007.

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14. Attached hereto as Exhibit H is a true and correct copy of excerpts from the LegalMetric District Judge Report for the District of Delaware as of February, 2006.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed in Palo Alto, CA, on October 29, 2007.

Katherine Nolan-Stevaux

pa-1202930

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Kenneth L. Dorsney, hereby certify that on October 29, 2007, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on October 29, 2007, I have Electronically Mailed the document to the following person(s):

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EXHIBIT A

Priority ✓
Send ✓
Enter ✓
Closed
JS-5/JS-6
JS-2/JS-3
Scan Only

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MEDEGEN MMS, INC.,

Plaintiff,

v.

ICU MEDICAL, INC.,

Defendant.

Case No. SA CV 06-619 MRP (ANx)

ORDER DISMISSING ICU'S COUNTERCLAIMS WITHOUT PREJUDICE

Following this Court's order granting Summary Judgment of Noninfringement to ICU, ICU sought trial of its counterclaims for declaratory judgment of invalidity and inequitable conduct. Medegen objected. The Court asked the parties to brief the issue of jurisdiction and discretion to try the counterclaims.

Having read and considered Medegen's and ICU's respective Memoranda Regarding Counterclaims, the Court concludes that even after noninfringement has been found, there is still a case or controversy adequate to support jurisdiction over a declaratory judgment counterclaim. *Fort James Corp. v. Solo Cup Co.*, 412 F.3d 1340, 1348 (Fed. Cir. 2005) (citing *Altvater v. Freeman*, 319 U.S. 359 (1943)). However, the issue of whether to hear ICU's counterclaims is a matter within the

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Court's discretion. *Nestier Corp. v. Menasha Corp.-Lewisystems Div.*, 739 F.2d 1576 (Fed. Cir. 1984). Accordingly, in consideration of the time and expense which would be involved in a further trial, the Court exercises its discretion to enter judgment in the matter without trial of ICU's counterclaims.

The Court dismisses ICU's counterclaims without prejudice as moot.

IT IS SO ORDERED.

DATED: October 17, 2007

Hon. Mariana R. Pfaelzer
United States District Judge

EXHIBIT B

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MEDEGEN MMS, INC.,

Plaintiff,

v.

ICU MEDICAL, INC.,

Defendant.

Case No. SA CV 06-619 MRP (ANx)

JUDGMENT OF NONINFRINGEMENT OF UNITED STATES PATENT NO. 5,730,418 C1

Pursuant to this Court's Order of September 14, 2007 Granting Defendant ICU's Motion for Summary Judgment of Noninfringement, which was granted upon consideration of ICU's Motion for Summary Judgment of Noninfringement, Medegen's Opposition and ICU's Reply, as well as all submitted supplemental memoranda, declarations and exhibits by both parties, including all relevant authorities cited, and the arguments and material presented at the hearing,

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IT IS HEREBY ORDERED, ADJUDGED, AND DECREED:

1. ICU's CLC2000 connector does not infringe United States Patent No. 5,730,418 C1.
2. Medgen's Complaint is hereby DISMISSED WITH PREJUDICE.

IT IS SO ORDERED.

DATED: October 17, 2007

Mariana R. Pfaelzer
Hon. Mariana R. Pfaelzer
United States District Judge

EXHIBIT C

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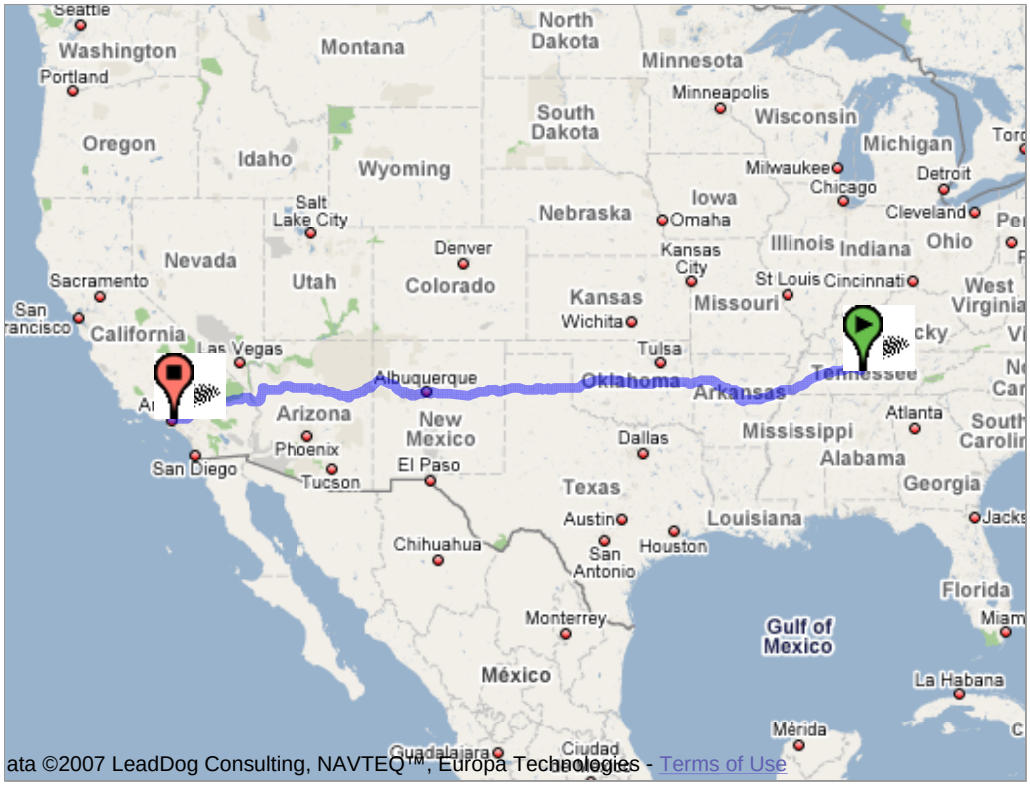
EXHIBIT D

Start **Franklin, TN**
End **Los Angeles, CA**
Travel **1,999 mi – about 1 day 5 hours**



Franklin, TN

Drive: 1,999 mi – about 1 day 5 hours

1.	Head **southwest** on **Main St** toward **5th Ave S**	240 ft
2.	Turn **right** at **5th Ave N**	0.1 mi 1 min
3.	Turn **left** at **TN-96**	11.8 mi 18 mins
4.	Turn **left** at **TN-100/TN-96**	5.4 mi 8 mins
5.	Take the **TN-96 W** ramp to **Dickson/I-40**	0.2 mi
6.	Merge onto **TN-96**	4.7 mi 9 mins
7.	Turn **left** to merge onto **I-40 W**	171 mi 2 hours 29 mins
8.	Take exit **10B** to merge onto **I-40 W** Passing through Arkansas Entering Oklahoma	475 mi 6 hours 57 mins
9.	Take the exit onto **I-35 S/I-40 W/Stanley Draper Expy/US-62 W** toward **Amarillo** Continue to follow I-40 W	1,216 mi 16 hours 57 mins

Passing through Texas, New Mexico, Arizona
Entering California

10.	Merge onto **I-15 S**	58.6 mi 51 mins
11.	Take the exit onto **I-15 S** toward **Los Angeles/San Diego**	14.0 mi 13 mins
12.	Take the exit onto **I-10 W** toward **Los Angeles**	40.7 mi 40 mins
13.	Merge onto **US-101 N**	1.0 mi 1 min
14.	Take exit **2C** for **Spring St**	0.1 mi
15.	Turn **right** at **N Spring St**	0.4 mi 2 mins
16.	Turn **right** at **Tom Bradley Blvd**	210 ft

Los Angeles, CA

These directions are for planning purposes only. You may find that construction projects, traffic, or other events may cause road conditions to differ from the map results.

Start **Wilmington, DE**
End **Franklin, TN**
Travel **789 mi – about 12 hours 28 mins**

Wilmington, DE

Drive: 789 mi – about 12 hours 28 mins

1.	Head **northwest** on **E 4th St** toward **N Market St**	0.3 mi 1 min
←	2. Turn **left** at **N Washington St**	0.1 mi 1 min
→	3. Turn **right** at **W 2nd St**	0.3 mi 1 min
←	4. Slight **left** to merge onto **I-95 S** toward **Delaware Memorial Bridge/ Baltimore** Partial toll road Entering Maryland	96.2 mi 1 hour 36 mins
	5. Take exit **27** to merge onto **Capital Beltway/I-495 W** toward **Silver Spring** Entering Virginia	22.8 mi 25 mins
	6. Take exit **49** to merge onto **I-66 W** toward **Front Royal/Manassas**	64.4 mi 1 hour 2 mins
	7. Take exit **1A** to merge onto **I-81 S** toward **Roanoke** Entering Tennessee	376 mi 5 hours 48 mins
	8. Take exit **1B** to merge onto **I-40 W** toward **Knoxville**	208 mi

		3 hours 8 mins
9.	Continue on **I-24 E** (signs for **I-440 W/Chattanooga/Memphis/I-24 E**)	0.8 mi 1 min
10.	Take exit **53** to merge onto **I-440 W** toward **Memphis**	2.6 mi 3 mins
11.	Take exit **5** to merge onto **I-65 S** toward **Huntsville**	15.0 mi 14 mins
12.	Take exit **65** for **TN-96** toward **Franklin/Murfreesboro**	0.2 mi
13.	Turn **right** at **Murfreesboro Rd/TN-96** Continue to follow TN-96	2.6 mi 6 mins
14.	Continue on **3rd Ave S**	0.1 mi 1 min
15.	Turn **right** at **Public Square**	125 ft
16.	Turn **left** to stay on **Public Square**	256 ft
17.	Turn **right** at **Main St**	0.1 mi

Franklin, TN

These directions are for planning purposes only. You may find that construction projects, traffic, or other events may cause road conditions to differ from the map results.

EXHIBIT E

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

ICU MEDICAL, INC.,

Plaintiff,

v.

B. BRAUN MEDICAL, INC.,

Defendant.
/

No. C 01-03202 CRB

CLAIM CONSTRUCTION ORDER

This suit involves the alleged infringement of United States Patent No. 6,669,673 (the "'673 Patent"). The '673 Patent discloses a valve to be used in medical environments to connect two fluid-carrying instruments allowing transmission of fluids between them. Now before the Court is the task of construing certain claim terms over which the parties remain in dispute.

A. Legal Standard

Patent infringement analysis involves two steps. The first step is to construe the asserted claims, and the second step is to determine whether the accused method or product infringes any of the claims as properly construed. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd 517 U.S. 370 (1996). The first step, construction of the patent claims, is a matter of law and thus the responsibility of the court. See id. at 979.

"[I]n interpreting an asserted claim, the court should look first to intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). In examining

intrinsic evidence, the court should first look to the words of the claims themselves to define the scope of the patented invention. See id. Words in a claim "are generally given their ordinary and customary meaning." Id.

The specification is also examined "to determine if the presumption of ordinary and customary meaning is rebutted." Brookhill-Wilk 1 v. Intuitive Surgical, 334 F.3d 1294, 1298 (Fed. Cir. 2003) (citations omitted). The presumption of ordinary meaning may be rebutted in two ways. First, the inventor can rebut ordinary meaning where she "has disavowed or disclaimed scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Id. at 1299 (citations omitted). Second, the patentee may "act[] as his or her own lexicographer [by] clearly set[ting] forth a definition of the term different from its ordinary and customary meaning." Id. (citations omitted). With respect to this second method of redefinition, the Federal Circuit has recently established that this may be done "by implication," that is, by "[using] a claim term throughout the entire patent specification, in a manner consistent with only a single meaning." Irdeto Access, Inc. v. Echostar Satellite Corp., 383 F.3d 1295, 1301 (Fed. Cir. 2004) (quoting Bell Atlantic Network Services, Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1271 (Fed. Cir. 2001)). This is accomplished where the patent "repeatedly, consistently, and exclusively" uses the term such as to indicate "the patentee's clear intent to . . . limit the term." Id. at 1302.

Much of the parties' dispute in the present construction centers around their different views of how this Court should determine whether the terms at issue have an "ordinary and customary" meaning. Braun's argument relies, in part, on their position that many of the terms in the claim do not possess any specialized meaning to those of skill in the art and thus must be defined by the usage of the terms in the specification. ICU's view is that the terms in the claims can be defined according to the generalized, non-technical meanings that would be understood by any layperson. In this regard, ICU's argument is that this Court's claim construction should begin with the definition provided by a general usage dictionary. Braun's argument is that the specification acts as the primary source for defining the terms.

Both parties' positions find at least some basis in law. Braun's position is supported by one line of cases which provides that "where evidence such as expert testimony or technical dictionaries demonstrates that artisans would attach . . . no meaning to the claim term independent of the specification 'general-usage dictionaries are rendered irrelevant with respect to that term.'" Irdeto Access, 383 F.3d at 1300 (quoting Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n, 366 F.3d 1311, 1321 (Fed. Cir. 2004)). ICU's position is bolstered by a second line of cases, which state that "[i]t is well settled that dictionaries provide evidence of a claim term's ordinary meaning" and that where a particular term does not have "an established specialized meaning in technical dictionaries . . . of the relevant field of art . . . standard dictionaries of the English language are the proper source of ordinary meaning of the phrase." Inverness Med. Switz. Gmbh v. Princeton Biomeditech Corp., 309 F.3d 1365, 2369 (Fed. Cir. 2002) (citations omitted).

This Court acknowledges that there is tension between these cases, and that this tension will almost certainly be resolved by the Federal Circuit in the coming months. See Phillips v. AWH Corp., 376 F.3d 1382 (Fed. Cir. 2004) (granting petition for rehearing en banc and directing briefing, inter alia, on the relative roles that dictionaries and the specification play in claim construction). However, with respect to the case at bar, this Court finds that the tension does not preclude decision because the parties positions are similar enough that the result would be the same regardless of which line of cases is adopted. Both parties in their briefs have agreed that a general-usage dictionary should play some role in this claim construction. Cf. ICU Opening Brief, at 11 (arguing for use of dictionary definition of "flexible element") with Braun Brief, at 10 (arguing for use of dictionary definition of "flexible"). The focus of the parties' dispute is therefore narrower than the dispute that Phillips will resolve. That is, the parties here merely dispute what weight should be given to the available dictionary definitions when compared to the specification. ICU argues that the dictionary definitions represent "ordinary meaning" and thus there should be a strong presumption that their full breadth is claimed unless something in the specification expressly narrows the scope of the terms. See Brookhill-Wilk 1, 334 F.3d at 1298-99 (claims given full scope unless patentee has expressly disavowed scope of coverage). Braun argues that no such presumption should be given, and that instead this Court should evaluate all of the intrinsic evidence–particularly the

specification–in order to come to a conclusion with respect to the scope of the terms. See Irdeto Access, 383 F.3d at 1300 ("absent . . . an accepted meaning [in the art, the court] construe[s] a claim term only as broadly as provided for by the patent itself.") (citing J.T. Eaton & Co. v. Atl. Paste & Glue Co., 106 F.3d 1563, 1570 (Fed. Cir. 1997)). This Court, however, does not view Irdeto Access as foreclosing any reference to general-usage dictionaries or, for that matter, common sense in construing terms that lack any specialized meaning. To so hold would mean that novel phrases used to describe novel ideas would always have to be defined ad nauseam in a patent specification when resort to simple, commonly understood words in the English language would provide sufficient meaning to satisfy the patent's "notice function." See Irdeto Access, 383 F.3d at 1303. See also RF Delaware, Inc. v. Pacific Keystone Tech., Inc., 326 F.3d 1255, 1263 (Fed. Cir. 2003) (holding that "when a claim term is expressed in general descriptive words, it typically will not be limited" by the preferred embodiment or by other claims). It would also mean that in cases, such as this one, where the specification does not use disputed terms or uses them only sparingly, such terms would be rendered meaningless, making the process of claim construction impossible. Irdeto Access itself refused to go so far, restricting its holding to the particular circumstances in that case in which the applicant had "unequivocally directed the patent examiner, as well as the public, to the specification as the complete source of meaning for the disputed terms." Id. Moreover, in that case the court also limited its holding to the fact that the specification had "repeatedly, consistently, and exclusively" used the disputed term in a manner consistent with a narrow interpretation. Id.

In short, this Court finds it enough to hold that in the instant case the ordinary meaning of a term may be determined by reference to a general usage dictionary. However, because this Court finds that none of the disputed terms have specialized meanings in the relevant art,[1] they will not obtain the strong presumption that is provided for in the relevant cases. Instead, this Court will resort to the specification to determine whether the ordinary meaning should be abandoned in favor

[1]Braun's expert argues that none of the disputed terms have specialized meanings, while ICU's expert states that an individual skilled in the relevant art would recognize the terms to mean what ICU says they mean. ICU's expert, however, cites no specialized dictionaries, treatises or other support of the specialized status of the relevant terms. Moreover, the patent itself is often not internally consistent in its use of the terms: it uses one term (e.g. "flexible element") to refer to an object in the claims and another (e.g. "seal") to refer to the same object in the specification. For these reasons, the Court finds that the none of the disputed terms have specialized meanings.

of a meaning that is more consistent with the use of the term in context. In any event, the overarching rule remains that the claim serves as the primary reference point for the meaning of the terms. See Teleflex, Inc. v. Ficosa North America Corp., 299 F.3d 1313, 1328 (Fed. Cir. 2002) (absent a clear statement regarding scope, the court is constrained to follow the language of the claim rather than the written description).

B. Flexible Element

ICU argues that the term "flexible element" should be defined as "portion that is capable of being bent or flexed" while Braun argues that it should mean an element that is "capable of being bent without breaking, easily bent" but "not using mechanical or moving parts such as springs or diaphragms." Revised Joint Claim Construction and Prehearing Statement for '673 Patent ("RJCCPS") at 3. Thus, Braun's definition is narrower than ICU's in two respects: 1) "flexible" means flexible without breaking; and 2) "flexible" means not using mechanical or moving parts.[2]

1. Bent Without Breaking

The parties agree that the construction of the term "flexible" begins with its dictionary definition. ICU Opening Brief at 11; Braun Brief at 10. The parties further agree that the 1987 edition of the Random House Unabridged Dictionary is the proper general-usage dictionary for this claim construction. ICU Opening Brief at 11; Braun Brief at 10. Random House defines "flexible" as:

> 1. capable of being bent, usually without breaking; easily bent . . . 2. susceptible to modification or adaptation.; adaptable . . . ; 3. willing or disposed to yield; pliable . . . 4. a flexible substance or material, as rubber or leather.

Random House Unabridged Dictionary 733 (2d ed. 1987). This Court thus may easily dispose of Braun's limitation that a "flexible" object must be able to be bent without breaking. The dictionary definition makes no such categorical statement. Both parties would have been more consistent with their dependence on the dictionary had they argued that "flexible" means "usually without breaking." Accordingly, this Court will construe the term as including structures that are capable of being bent, but usually without breaking.

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[2]Braun also contends that this Court's construction of "flexible element" must incorporate the other requirements of the object stated in the claim. However if this Court were to read those other limitations into the definition of the term then the claim would become redundant.

This construction is consistent with the use of the term in the patent. The claim states that the flexible element must be "movable between an uncompressed position . . . and a compressed position," while also being able to "flex[] to accommodate axial compression." Col. 16:4-12. The specification refers to the "seal"[3] as being "reusable," and "resilient." Col. 2:43-44, 3:35. A construction of the term "flexible" as being easily broken upon compression would conflict with these statements and thus is excluded. However, a construction of the term as being so resilient as to stand up to very strong compression such that it could never be broken would define term in a way not supported by the patent.

2. Mechanical Parts, Springs and Diaphragms

Braun is incorrect in asserting that the specification "disavows or distinguishes" the "flexible element" from "prior art valves and connectors that use 'springs or diaphragms'" such that an interpretation of the "flexible element" including mechanical parts is foreclosed. Braun Brief at 14. The specification's description of the advantages of the invention over prior art devices cannot limit the definition of the claim unless it constitutes a clear disavowal. See Brookhill-Wilk 1, 334 F.3d at 1301 ("Advantages described in the body of the specification, if not included in the claims, are not per se limitations to the claimed invention.") (citations omitted); Astrazeneca AB, Aktiebolaget Hassle, KBI-E, Inc. v. Mutual Pharmaceutical Co., Inc., 384 F.3d 1333, 1340 (Fed. Cir. 2004) (criticism of prior art may be a disavowal if implication is clear from discussion of particular feature of the invention). Contrary to Braun's reading of the patent, it can not be said that the specification "repeatedly, consistently and exclusively" discusses seals as not having mechanical parts. Irdeto Access, 383 F.3d at 1303.

The specification describes the prior art mechanical connectors as inferior because they were more prone to malfunction upon repeated use. Col. 1:35-46. The specification does not say that the invention in the '673 Patent will never have mechanical parts. Nor does it say that all inferior designs have mechanical parts. Col. 1:35 (stating that prior art connectors "*often* have mechanical or moving parts" (emphasis added)). Instead, the specification describes the claimed invention as

[3]The parties agreed at oral argument that the term "seal" in the specification is equivalent to the term "flexible element" in the claim. Thus in construing the term "flexible element," this Court will take into consideration the use of the term "seal" in the specification.

superior to prior art devices because "the *fewer* the mechanical parts the more these connectors can be relied on . . . ." Col. 1 44-45. Thus the specification merely states that it is preferable for medical valves of the type disclosed in the '673 Patent to have few, although not necessarily zero, mechanical parts. If Braun's interpretation of this portion of the specification as a clear disavowal of all flexible elements using mechanical parts were accepted, then the claimed invention could also never have "moving parts." See Col. 1:41-43 ("[t]he more mechanical or *moving parts* such as springs and diaphragms, the more likely that they will function improperly." (emphasis added)). However, the claimed invention undisputedly does have at least one moving part–the flexible element itself. Col. 9:37 (describing the seal in one preferred embodiment as a "movable part[]").

Accordingly, this Court construes the term "flexible element" to mean a portion of the valve that is capable of being bent, usually without breaking.

C. Compressed Position

ICU argues that the term "compressed position" should be interpreted to mean "location in which the flexible element is depressed into less space in the cavity." RJCCPS at 4. Braun contends that the proper definition of the phrase is "the position of the flexible element when it is under axial compression and fully opens the valve." Id. The parties' central point of contention on this issue is whether "compressed position" requires full or complete compression, or put differently, whether partial compression is within the scope of the term. The parties also dispute whether the compression referred to is necessarily axial compression, or includes other directions of compression as well.

1. Fully Open

Reading "compressed position" in the context of the claim and specification,[4] it becomes clear that the term refers to a configuration of the flexible element in which the valve is in an open state and fluid is allowed to move through it. Col. 16:5-8 (describing "a compressed position in which fluid flow is permitted through said valve"). Thus the parties' disagreement can be described

[4]The parties agree that the terms "compressed position" and "uncompressed position" in the claim are equivalent to the terms "compressed state" and "decompressed state," respectively, in the specification. Therefore, the use of the latter terms in the specification is relevant to the construction of the former terms.

as whether the flexible element can be in a "compressed position" even though the flexible element may still be partially obstructing the fluid from flowing through the valve.

Braun's argument focuses on Claim 1's use of the word "between" in its statement that the flexible element is "movable between an uncompressed position . . . and a compressed position . . . " Col. 16:5-8. According to Braun, this requires that there is only one single compressed position in which the flexible element is fully compressed. However, there is nothing inherent in the word "between" that implies that the valve be fully opened. The flexible element could just as easily be understood to move "between" a closed position and a partially open position. Although Braun insists that ICU's understanding is an attempt to rewrite the claim language, it is Braun's interpretation that seeks an impermissible revision. Under Braun's construction the claim would be rewritten from "a compressed position in which fluid is permitted through said valve" to "a fully compressed position in which maximum fluid flow is permitted through said valve." This Court is not permitted to do so, and thus Braun's proposed limitation is rejected.

2. Axial Compression

Braun also argues that the compression referred to by the terms "compressed position" and "uncompressed position" may only be axial compression. This time Braun is correct. ICU contends that the claim contains no such limitation and gives as examples statements in the specification indicating that the flexible element exerts radial compression on the inner wall of the valve in both the compressed and uncompressed positions:

> The seal in the decompressed state . . . bears against the wall structure near the opening to seal the opening . . . A fluid tight seal is maintained between the seal section and the wall structure as the seal is moved into the compressed state. The seal section bears against the wall structure . . . .

Col. 3:38-48. However ICU must rip this excerpt from its context in order to retrieve the desired meaning. Immediately before this portion, the specification states "[t]he third feature is that the resilient seal is adapted to be moved into a compressed state upon insertion of the tip of the medial [sic] implement into the opening and returns to a decompressed state upon removal of the tip." Col. 3:35-38. It is clear from this statement that the source of the compression is the insertion of the medical implement into the opening of the valve. The direction of that compression is axial, that is, it moves along the axis of the valve. See Random House Unabridged Dictionary 145 (2d ed. 1987)

(defining axial as "situated in or on an axis"). The compression referred to in the excerpt cited by ICU is the force applied by flexible element against the inner wall of the valve while it under axial compression from the medical implement. If, on the other hand, ICU is claiming that the statement that the flexible element "bears against the wall structure" in the "decompressed state" demonstrates non-axial compression, then ICU refutes its own argument. As discussed more thoroughly below, it cannot be the case that the flexible element is experiencing any compression from the medical implement in the "uncompressed position."

In using the terms "compressed," "uncompressed" and "decompressed" the patent repeatedly, consistently and exclusively refers to axial compression. For example, the claim discusses the wall of the flexible element as "flexing to accommodate axial compression." Col. 16:11-12. The specification states that "[a] two-way valve eliminating dead space is used which includes a seal which, upon being *compressed by the medical implement*, is pierced to open the valve and reseals upon being decompressed . . . ." Col. 1:22-26 (emphasis added). ICU has failed to offer any statement in intrinsic evidence that contradicts this meaning. As such, this Court finds that the terms "compressed position" and "uncompressed position" refer only to axial compression.

Accordingly, the term "compressed position" is construed as the position of the flexible element when it is under axial compression from a medical implement[5] and opens the valve.

E. Uncompressed Position

ICU argues that the term "uncompressed position" refers to the "location in which the flexible element is not depressed into less space in the cavity" while Braun states that it means "the position of the flexible element when it is not under axial compression and closes the valve." RJCCPS at 3. The only difference in the parties' positions is whether or not the flexible element may remain under some axial compression in the "uncompressed position."

At the outset, ICU's attempt to turn "un" into "some" clearly conflicts with ordinary meaning. ICU argues that its construction is supported by a statement in the specification that "[t]he seal has a lip . . . [that] upon assembly . . . is compressed between the locking elements." In

[5]The addition of "from a medical implement" is described under the Court's construction of "uncompressed position."

addition, ICU maintains that the flexible element is always under axial compression by atmospheric pressure. While both of these creative arguments do confirm that there is some axial force acting on the flexible element in its uncompressed position, they still mischaracterize the relevant term. Clearly "uncompressed" refers to a lack of compression. This begs the question as to what source of compression is referenced. The logical answer–supported by the patent's repeated use of the relevant terms–is that the compression is caused by the insertion of a medical implement into the valve. Col. 1:23-25 (the valve "includes a seal which, upon being compressed by a medical implement"); Col. 3:35-38 ("The third feature is that the resilient seal is adapted to be moved into a compressed state upon insertion of the tip of the medial [sic] implement into the opening and returns to a decompressed state upon removal of the tip . . . ."); Col. 42-45 ("In the compressed state, the seal section is pushed by the delivery end of the medical implement . . . ."); Fig. 5 (depicting compression of the flexible element by a syringe).

The term "uncompressed position" is therefore construed as the position of the flexible element when it is not under axial compression from a medical implement and closes the valve.

F. Ring Shaped Support

ICU argues that the term "ring shaped support" should be construed as "a circular-shaped structure that serves as a foundation, prop, brace or stay." Braun seeks a much narrower construction, limiting the term to "an annular cuff into which the flexible element fits." Braun cites as support for its limitation a portion of the preferred embodiment labeled the "annular cuff 28." Col. 7:29-38. However, in doing so Braun seeks to impermissibly import a limitation contained in the preferred embodiment onto the claim language. See Teleflex, Inc. v. Ficosa North America Corp., 299 F.3d 1313, 1328 (Fed. Cir. 2002) (cautioning against "limiting the claimed invention to preferred embodiments or specific examples in the specification" (citations omitted)). The term "ring shaped support" uses plain words and the phrase has an ordinary meaning based on the constituent terms' general usage. Braun's attempt to inject ambiguity where there is none is rejected.

ICU's interpretation, on the other hand, simply redefines the term "ring shaped support" using dictionary definitions that in no way clarifies the scope of the term. This Court finds little use

in doing so and instead agrees with ICU's alternative interpretation that the term is unambiguous and construction is unnecessary. RJCCPS at 4.

G. Diameter

ICU defines "diameter" as a "straight line passing through the center of an object from side to side." RJCCPS at 4. Braun counters that it means "a straight line passing through the center of a circle and meeting the circumference or surface at each end." Id. The disagreement, then, concerns whether a "diameter" can pass through a non-circular object.

Once again, both parties begin their definition of the term with the dictionary, which defines "diameter" as:

> 1 . . . a. a straight line passing through the center of a circle or sphere and meeting the circumference or surface at each end. b. a straight line passing from side to side of any figure or body, through its center. 2. The length of such a line. 3. the width of a circular or cylindrical object.

Random House Unabridged Dictionary 547 (2d ed. 1987). The parties are consequently asking this Court to choose between two equally applicable dictionary definitions. In this context, the Federal Circuit has instructed that,

> [b]ecause words often have multiple dictionary definitions . . . the intrinsic record must always be consulted to identify which of the different possible dictionary meanings of the claim terms in issue is most consistent with the use of the words by the inventor . . . .If more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all such consistent meanings.

Texas Digital Sys. v. Telegenix, Inc., 308 F.3d 1193, 1203 (Fed. Cir. 2002); Blistad v. Wakalopulos, No. 03-1528, 2004 WL 2248109 (Fed. Cir. Oct. 7, 2004). Under this rule, this Court finds that Braun's definition is "most consistent" with the use of the word in the patent.

ICU points to two examples in the specification that it contends demonstrates the correctness of its interpretation. First, ICU points to the statement in the context of the description of an embodiment that "during compression of the seal 36a, the diameter of the ringed wall portions 94 expand outward in the radial direction." Col. 12:13-15. However the "ringed wall" is circular and thus is consistent with Braun's definition. Second, ICU cites a preferred embodiment that "has a bell-shaped skirt and an upper, preferably cylindrical, conduit." Col. 6:65-67. Apparently it is ICU's contention that the excerpts use of the term "preferably" alludes to the possibility of non-circular

shapes. The excerpt, however, doesn't even use the term "diameter." Moreover, the shapes it does refer to are circular, in that a cross section of a "bell-shaped skirt" or a "cylindrical" conduit would be a circle.

Each of the specification's uses of the term "diameter" correspond with circular objects. Col. 4:4-5 ("The O-ring elements have increasing diameters, with the smallest diameter element begin [sic] adjacent the proximal end of the cavity."); Col. 7:12-24 (referring to the "outer diameter" of the "upper conduit" in Figs. 4, 5 and 19, which the diagrams depict as circular).

The term "diameter" shall thus be construed as proposed by Braun.

H. Substantially Flat and Substantially Flush

The Court finds that the terms "substantially flat" and "substantially flush" are unambiguous and therefore require no construction.

I. Support Member

ICU proposes that this term be defined as "a constituent part that serves as a foundation, prop, brace or stay." RJCCPS at 4. Braun defines the term as "a member that supports the valve in a manner that allows it to be removably attached to a fluid dispenser." Id. Braun's definition therefore attempts to define the term according to the surrounding claim language, which recites: "The valve of claim 1, wherein said medical valve further comprises a support member enabling said valve to be removably attached to a fluid dispenser." Col. 16:28-31. Braun's definition also adds a further limitation–that the "manner" of support provided by the support member relates to its ability to enable the valve to be removably attached to a fluid dispenser.

The specification discusses the "support member" in the following context:

> The fifth feature is that the medical valve includes a support member connected to the spike which seals off the distal end of the cavity. The support member may have a Luer-Lock type connector element that enables the valve to be removably attached to, for example, a fluid line connected to a patient. The support member may also be in the form of an adaptor that enables the valve to be removably attached to a fluid dispenser or container.

Col. 4:26-33. This description reveals that there is nothing inherent in "the manner" the support member supports the valve that relates to its ability to be "removably attached to a fluid dispenser." In fact, this excerpt demonstrates that the support member may allow the valve to be removably attached to a fluid dispenser either by having a part that is a "Luer-Lock type connector" or by itself

being in the form of an adaptor that provides that ability. Braun's limitation is consequently refuted by the intrinsic evidence.

Accordingly, the term "support member" shall be construed in the manner proposed by ICU.

J. Removably Attached to a Fluid Dispenser

The Court finds that this phrase is unambiguous and therefore does not require construction.

K. Single Molding

Claim 5 discloses "[t]he valve of claim 1, wherein said flexible element comprises a single molding." Col. 16:32-33. ICU argues "single molding" means "formed from a single mold" while Braun contends it means "that the flexible element must be formed from a single mold." RJCCPS at 5. The parties both agree that the term "single molding" means "formed from a single mold." The parties also agree that it is the flexible element that is formed from a single mold. ICU Reply Brief at 15. Thus there is no real dispute with respect to the construction of this term. Because Braun's definition is redundant, the Court will give the term the construction offered by ICU.

L. Rigid Member

The only dispute with respect to the construction of this term is the definition of the word "rigid." See RJCCPS at 5. ICU argues that "rigid" means "stiff," while Braun proposes that it be construed as "stiff or unyielding, not pliant or flexible." Id. In the Court's view, neither definition adds clarity to the scope of the term and therefore both are rejected. The term is unambiguous and therefore no construction is necessary.

IT IS SO ORDERED.

Dated: November 8, 2004

/s/
CHARLES R. BREYER
UNITED STATES DISTRICT JUDGE

EXHIBIT F

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

ICU MEDICAL, INC.,

Plaintiff,

v.

B.BRAUN MEDICAL INC.,

Defendants.

/

No. C 01-3202 CRB

ORDER RE: MOTIONS FOR SUMMARY JUDGMENT AND SCHEDULING TRIAL

Plaintiff and Counterclaim Defendant ICU Medical, Inc. ("ICU") brought this suit against Defendant and Counterclaimant B.Braun Medical, Inc. ("Braun") for infringement of U.S. Patent No. 5,928,204 ("the '204 patent") and U.S. Patent No. 6,669,673 ("the '673 patent") by manufacturing and selling a specialized needleless medical connector. The patents relate to a medical valve for use in controlling the flow of fluid between two medical implements. The alleged infringing device is Braun's Ultrasite valve.

ICU and Braun cross-move for summary judgment on the issue of whether the Ultrasite valve[1] infringes the '673 patent. Braun also seeks summary judgment of

[1] In late 2004, Braun made a modification to the Ultrasite valve by changing the molds used in manufacturing the piston component to remove an alleged "taper" in the piston skirt. The modified valve will be referred to in this Order as the Ultrasite valve with modified piston. Otherwise, the term "Ultrasite valve" will refer to both the unmodified Ultrasite valve and the Ultrasite valve with modified piston.

non-infringement of both the '673 and '204 patents by the Ultrasite valve with modified piston. Finally, ICU moves for summary judgment that the '673 patent is not unenforceable due to inequitable conduct on the part of the patentee.

Having carefully considered the parties' papers, and with the benefit of oral argument on February 11, 2005, the Court hereby resolves the motions as follows:

1. ICU's motion for summary judgment that Braun's Ultrasite valve infringes the '673 patent is GRANTED in part as to claims 1-2 and 5-6, and DENIED in part as to claim 3.
2. Braun's motion for summary judgment that the Ultrasite valve does not infringe the '673 patent is DENIED in part as to claims 1-2 and 4-6, and GRANTED in part as to claim 3.
3. Braun's motion for summary judgment that the Ultrasite valve with modified piston does not infringe the '673 and '204 patents is GRANTED.
4. ICU's motion for summary judgment of no inequitable conduct is DENIED.

BACKGROUND

The administration of medication in hospital and medical settings routinely involves the use of connectors and adaptors for facilitating the movement of fluids (e.g., drugs and intravenous solutions) between medical implements. Since the ready passage of fluids through the connectors and adaptors is often critical to patient survival, it is important that they operate reliably and repeatedly. Both Braun and ICU are providers of needleless medical connectors.

Braun's Ultrasite valve is a needle-free, capless, swabbable valve. It contains a piston made of flexible material. When the piston is in its uncompressed state, it seals against the housing of the valve preventing fluid flow through the valve. In this state, the wall of the piston is relatively flat. When a syringe or other appropriate medical device is connected to the valve, the piston is compressed causing the piston wall to buckle. The compressed piston no longer completely seals against the valve housing because the portion of the piston that seals against the housing is moved to a location where there are

channels in the housing. When the piston is compressed, fluid can flow through the valve.

ICU is the assignee of two patents (the '673 and '204 patents) for a closed system, needleless valve device which automatically reseals after administering medication using a medical implement that directly connects with the system without the need of any intermediary needles, caps, or adaptors.

I. THE '673 PATENT

Independent claim 1 reads:

> A medical valve for controlling the flow of fluid between a first medical implement and a second medical implement, said valve comprising:
> . . . .
> . . . a flexible element positioned in said cavity movable between an uncompressed position in which a portion of the flexible element bears against the wall structure near said opening and obstructs fluid flow through said valve and a compressed position in which fluid flow is permitted through said valve, said flexible element comprising a wall with an inner surface and an outer surface, the wall flexing to accommodate axial compression of said flexible element, said flexible element comprising an end fitting against a ring shaped support to assist in securing said flexible element in said cavity, said flexible element in said uncompressed position comprising a first external diameter near said opening, a second external diameter in said main portion, said second diameter being smaller than said first diameter and said third diameter, and at least a portion of the outer surface of the wall of the flexible element between the second diameter and the third diameter being tapered.

U.S. Patent No. 6,669,673 (issued Dec. 30, 2003). Claims 2-6 are dependent claims from claim 1.

The Court issued its claim construction order regarding the '673 patent on November 8, 2004 (the "Markman Order"). In its Markman Order, the Court determined that the term "flexible element" should be defined as "a portion of the valve that is capable of being bent, usually without breaking." Markman Order at 7. The flexible element must be moveable from an uncompressed position, in which the valve is closed, to a compressed position, in which "it is under axial compression from a medical implement" and "the valve is in an open state and fluid is allowed to move through it." Id. at 9, 7. When the flexible element is in an uncompressed position, it must "bear against the wall structure" and "obstruct[] fluid flow" through the valve. '673 Patent Claim 1.

II. THE '204 PATENT

Independent claim 1 reads:

> A seal for use in selectively opening and closing a fluid pathway through a medical connector comprising a resilient seal element having a wall having a top end and a bottom end, said wall including at least two generally arcuate segments each having an outwardly extending portion, said segments intersecting one another and defining at least one space between where said segments intersect and a line tangential to the outwardly extending portions of both segments, and at least one segment proximate to said bottom end having a larger maximum diameter than a second segment nearer to said top end of said element.

U.S. Patent No. 5,928,204 (issued July 27, 1999). Claims 2-5 are dependent claims from claim 1.

DISCUSSION

ICU and Braun cross-move for summary judgment on the issue of whether Braun's Ultrasite valve infringes claims 1-3 and 5-6 of the '673 patent. Braun also seeks summary judgment of non-infringement by the Ultrasite valve with modified piston with regard to claims 1-6 of the '673 patent and claims 1-5 of the '204 patent. Finally, ICU moves for summary judgment that the '673 patent is not unenforceable due to inequitable conduct on the part of the patentee.

I. STANDARD OF REVIEW FOR SUMMARY JUDGMENT

Summary judgment is appropriate when the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). An issue is "genuine" only if there is sufficient evidence for a reasonable fact finder to find for the non-moving party. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248-49 (1986). A fact is "material" if the fact may affect the outcome of the case. See id. at 248. "In considering a motion for summary judgment, the court may not weigh the evidence or make credibility determinations, and is required to draw all inferences in a light most favorable to the non-moving party." Freeman v. Arpaio, 125 F.3d 732, 735 (9th Cir. 1997). A principal

purpose of the summary judgment procedure is to identify and dispose of factually unsupported claims. See Celotex Corp. v. Catrett, 477 U.S. 317, 323-24 (1986).

The party moving for summary judgment bears the initial burden of identifying those portions of the pleadings, discovery, and affidavits that demonstrate the absence of a genuine issue of material fact. See id. at 323. Where the moving party will have the burden of proof on an issue at trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party. See id. Once the moving party meets this initial burden, the non-moving party must go beyond the pleadings and by its own evidence "set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e). The non-moving party must "identify with reasonable particularity the evidence that precludes summary judgment." Keenan v. Allan, 91 F.3d 1275, 1279 (9th Cir. 1996) (quoting Richards v. Combined Ins. Co., 55 F.3d 247, 251 (7th Cir. 1995), and noting that it is not a district court's task "to scour the record in search of a genuine issue of triable fact"). If the non-moving party fails to make this showing, the moving party is entitled to judgment as a matter of law. See Celotex, 477 U.S. at 323.

II. INFRINGEMENT OF THE '673 PATENT

A patent infringement analysis involves two steps: claim construction and then applying the construed claim to the accused device. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995). The first step, construing the claims to determine their meaning and scope, has been held to be purely a matter of law. See Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998). The second step, application of the claim to the accused device, is a fact-specific inquiry. See Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998) ("[I]nfringement, whether literal or under the doctrine of equivalents, is a question of fact."). If each limitation of the patent claim is found in the accused device, either literally or as a substantial equivalent, the accused device infringes that claim. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29 (1997).

Summary judgment is appropriate in infringement suits when, drawing all reasonable inferences in favor of the non-moving party, there is no genuine issue of material fact. Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 988 (Fed. Cir. 1999). Because the relevant aspects of the accused device's structure and operation are undisputed in this case, the question of infringement collapses to one of claim construction and is particularly amenable to summary judgment. Id.

A. Literal Infringement

To establish literal infringement, the accused device must "contain each limitation of the claim exactly." Litton Sys., Inc. v. Honeywell Inc., 140 F.3d 1449, 1454 (Fed. Cir. 1998). The Court will proceed to compare the accused Ultrasite valve against all the claims and each of their limitations.

1. Claim 1 of the '673 patent

Claim 1 is the only independent claim of the '673 patent. It claims a medical valve for *controlling the flow of fluid* comprising a *flexible element* that: (1) *obstructs fluid flow* through the valve, (2) comprises *a wall flexing to accommodate axial compression* by a medical implement, (3) comprises *an end fitting against a ring shaped support*, and (4) is *tapered*. ICU asserts that Braun's Ultrasite valve satisfies each of these elements.

a. "Controlling the flow of fluid"

The Ultrasite valve plainly controls the flow of fluid from one medical implement to another. Braun's argument that its Ultrasite valve does not control fluid flow between two medical implements fails even under its own offered definition in which "control" means "to exercise restraint *or* direction over." Braun's Opposition Memorandum at 19 (quoting Random House Dictionary 442 (2d ed. 1983)) (emphasis added). Removing the implement inserted into the top of the Ultrasite valve restrains the flow of fluid as the piston moves toward its uncompressed position. Inserting a medical implement opens the valve, allowing fluid to flow between that implement and another implement connected to the other end of the valve. When the Ultrasite valve connects two medical implements, it

controls the flow of fluid by restraining the fluid within the valve and directing the flow from one implement to the other.

The term "control" should not be read so narrowly as to require the regulation of any "maximum" or "minimum" fluid flow. The preferred embodiments in the '673 patent work in a similar way (as does the Ultrasite valve) to control the flow of fluid between two medical implements: inserting a syringe or other medical implement opens the valve by exposing passageways that allow fluid to flow from one implement to the other. The '673 patent does not recite a medical valve that independently starts, shuts off, slows-down, or speeds-up the flow of fluids. To accept Braun's argument would exclude the elected embodiments of the '673 prosecution, and produce a highly disfavored result for which Braun provides insufficient support. Globetrotter Software, Inc. v. Elan Computer Group, Inc., 362 F.3d 1367, 1381 (Fed. Cir. 2004) (vacating summary judgment of non-infringement where accused infringer's claim interpretation would have excluded patent's preferred embodiment; such an interpretation is "rarely, if ever, correct.").

b. "Flexible element" that "obstructs fluid flow"

Braun's Ultrasite valve also comprises a flexible element that obstructs fluid flow through the valve. In its claim construction, the Court construed the disputed claim language as follows. The term "flexible element" means "a portion of the valve that is capable of being bent, usually without breaking." Markman Order at 7. ICU does not assert that the entire piston assembly (including the piston component, rigid plug, and spring) constitutes the flexible element. Rather, ICU contends that only the piston component, or piston, infringes the "flexible element" limitation of claim 1.[2] ICU's Reply Memorandum at 4-5.

The piston is clearly a flexible element under the claim language. It is made in a single molding of an elastomeric material, which allows it to flex or bend without

[2] For the purposes of this Order, the term "piston" refers to the piston component as opposed to the entire piston assembly.

breaking. The piston bends at several points during operation of the valve. In the uncompressed position, the lip of the piston flexes in response to radial pressure as it is squeezed into the neck of the housing. The shoulder of the piston flexes when it is pressed against the housing shoulder. The neck of the piston also flexes during insertion of the rigid plug and spring at assembly. The piston skirt flexes in response to axial pressure when it is moved into a compressed position by a medical implement.

Braun contends that the elastomeric piston is not "flexible" inside the valve because the rigid plug inserted into the neck of the piston is not flexible. The Court's construction, however, does not require that the flexible element must be bent, only that it is *capable* of being bent. Insertion of the rigid plug does not change the fact that the piston is still capable of being bent in response to pressure (e.g., radially from the rigid plug or housing wall, and axially from the medical implement), which is all the claim requires. Indeed, insertion of the rigid plug causes the piston neck to flex in response to radial pressure, and insertion of a medical implement causes the piston skirt to flex in response to axial pressure when it is moved into a compressed position.

Braun further contends that ICU's position is inconsistent with its earlier claim that the Ultrasite valve satisfies a "rigid sealing element" limitation in U.S. Patent No. 6,245,048 (the '048 patent). Claim 1 of the '048 patent recites "a rigid sealing element . . . movable between a first position in which said seal prevents fluid flow and a second position in which fluid flow is permitted . . . ." Braun's argument fails because ICU is not contending that the same features of the valve are both a "rigid sealing element" and a "flexible element." Rather, ICU refers to the stiffened lip and neck portion of the combined piston assembly as the "rigid sealing element," but only the piston component as the "flexible element." Although the Ultrasite piston assembly as a whole is rigid, the piston component remains flexible. It does not follow that a stiffened piston assembly cannot comprise a "flexible" piston which is capable of bending in response to pressure.

The piston also obstructs fluid flow through the valve. In an uncompressed position, the lip of the piston bears against the housing wall and the rigid plug to create a seal that obstructs fluid from entering the valve. The piston shoulder also bears against the internal housing wall and prevents fluid from flowing through the valve. Insertion of a medical implement pushes down on the rigid plug, which moves the piston from an uncompressed position to a compressed position in which fluid is allowed to flow through passageways in the valve.

Braun's argument that the rigid plug, not the piston, obstructs fluid flow through the valve is not supported by the evidence. In the Ultrasite valve, the fluid path is around the outside of the piston assembly, not through it. Even without the rigid plug, the piston bears against the housing wall near the valve opening and at the piston shoulder, blocking the passageways that allow fluid to flow through the valve. Although the piston component is hollow, a fluid barrier exists at the base where the piston is compressed between the luer nut and the housing wall. So even without a rigid plug, the piston obstructs fluid flow.

Moreover, Braun's contention that the piston or flexible element alone must obstruct fluid flow through the Ultrasite valve is not what the claim requires. Claim 1 is a "comprising" claim for "a medical valve . . . comprising . . . a flexible element . . . [that] obstructs fluid flow . . . ." A claim that incorporates the term "comprising" is "generally understood to signify that the claims do not exclude the presence in the accused apparatus . . . of factors in addition to those explicitly recited." Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 811-12 (Fed. Cir. 1999) (reversing summary judgment of non-infringement where accused device included features in addition to elements claimed in a "comprising" claim); see also Stiftung v. Renishaw PLC, 945 F.2d 1173, 1178 (Fed. Cir. 1991) (a claim "which uses the term 'comprising,' is an 'open' claim which will read on devices which add additional elements"). "The signal 'comprising' implements the general rule that absent some special circumstance or estoppel which excludes the additional factor, infringement is not avoided by the presence of

elements . . . in addition to those specifically recited in the claim." Vivid Techs., 200 F.3d at 811.

Here, Braun cannot escape infringement by pointing to other elements in the Ultrasite valve such as the rigid plug that also obstruct fluid flow. There are no special circumstances and Braun has not pointed to anything in the '673 prosecution history that would allow it to evade the general rule that an accused infringer cannot escape infringement by pointing to elements in his device that are in addition to those elements in the claimed invention. See id. Braun's Ultrasite valve infringes despite the fact that the piston component is not the only element obstructing fluid flow through the valve.

c. "A wall flexing to accommodate axial compression"

The Ultrasite valve also comprises a wall that flexes to accommodate axial compression. The claim recites "a flexible element . . . comprising a wall . . . flexing to accommodate axial compression." Braun's argument that there can be only one wall that flexes (its entirety) in the flexible element in response to axial compression is not what the claim requires. The claim describes a flexible element that comprises or includes "a wall" that flexes in response to axial compression, but may also include other parts that do not flex in response to axial pressure.[3] The claim should not be read to require that the entire piston must flex to accommodate axial compression. See Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988) ("Where a specification does not *require* a limitation, that limitation should not be read from the specification into the claims.").

Here, the piston component is the flexible element. Inserting a syringe or other medical implement moves the piston into a compressed position and causes the piston skirt to flex in response to axial pressure. Accordingly, the piston skirt is *a wall* that flexes to accommodate axial compression of the piston, and satisfies the claim limitation.

[3] As ICU correctly notes, the use of the indefinite article "a" in an open-ended, "comprising" claim does not limit that claim to the singular. KJC Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1356 (Fed. Cir. 2000) ("This court has repeatedly emphasized that an indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more' in open-ended claims containing the transitional phrase 'comprising.'").

d. "An end fitting against a ring shaped support"

Claim 1 of the '673 patent also requires that the flexible element has an "end fitting against a ring shaped support." In its claim construction, the Court found the term "ring shaped support" to be unambiguous. Markman Order at 11. In the Ultrasite valve, the piston component sits on top of the Luer nut, which makes up the bottom part of the body of the housing. Braun contends that the Luer nut presents nothing more than "a flat surface on which the piston assembly sits" and cannot constitute a "ring shaped support." Braun's Opposition Memorandum at 20. The top surface of the Luer nut, however, is not flat. The "annular sealing ring" on the face of the Luer nut includes a concentric series of ring-shaped ridges. The piston plainly fits against a ring-shaped support, which helps to secure the piston in the housing body, and satisfies the claim limitation.

e. "At least a portion . . . of the wall . . . being tapered"

The final limitation of claim 1 requires that a portion of the wall of the flexible element be "tapered" between the second and third diameters. The parties agree that "tapered" means "to make gradually diminished in width toward one end." Braun's Opposition Memorandum at 21. ICU asserts that the skirt of the piston component in the Ultrasite valve satisfies this limitation.

Braun does not refute the assertion that its unmodified Ultrasite valve meets the "taper" limitation. Indeed, the valve contains a slight taper along the skirt of the piston component. Braun states that the taper is a draft mold, or a well-known non-functional by-product of the manufacturing process. Nevertheless, the piston skirt gradually diminishes in width towards one end of the Ultrasite valve structure as the claim requires.

Braun contends, however, that to the extent a slight mold draft on the unmodified valve could be considered a taper, Braun has now removed it from the Ultrasite product. The piston component of the newly modified valve is no longer tapered. Instead, the piston skirt consists of straight walls. The question of whether the new, modified Ultrasite valve infringes the '673 patent is considered further below.

As to the unmodified Ultrasite valve, Braun has failed to raise any material issue of fact to rebut ICU's showing that it contains each limitation of claim 1 of the '673 patent. Consequently, the Court finds that the accused unmodified Ultrasite valve literally infringes claim 1 of the '673 patent.

2. Claim 2 of the '673 patent

Claim 2 of the '673 patent incorporates all the limitations in claim 1 and adds that an end of the flexible element in its uncompressed position near the opening must be "substantially flat." The lip of the Ultrasite valve's piston component is substantially flat. Braun contends, however, that "the end of the piston that is closest to the opening is substantially open, not flat." Braun's Opposition Memorandum at 23. But claim 2 does not require the end of the piston component to be both flat and disc-shaped as opposed to ring-shaped. Therefore, the Court finds that the accused unmodified Ultrasite valve literally infringes claim 2 of the '673 patent.

3. Claim 3 of the '673 patent

Claim 3 of the '673 patent incorporates all the limitations in claim 1 and adds that an end of the flexible element in its uncompressed position must be "substantially flush with the opening of said cavity of said body." ICU contends that "substantially" is a modifier implying "approximately" rather than "perfect." ICU's Reply Memorandum at 12; see also Liquid Dynamics Corp. v. Vaughan Co., 355 F.3d 1361, 1368-69 (Fed. Cir. 2004) (noting that the term "substantial" is a modifier implying "approximate," rather than "perfect"). But the Ultrasite valve's piston component is not even "approximately" flush with valve opening. Instead, it is recessed in the cavity of the valve near the opening. The lip of the piston component sits beneath the rigid plug, which in turn sits below the top surface of the valve opening. Therefore, the Court finds that the Ultrasite valve does not literally infringe claim 3 of the '673 patent.

4. Claim 5 of the '673 patent

Claim 5 of the '673 patent incorporates all the limitations in claim 1 and adds that the flexible element must comprise "a single molding." The parties agree that "comprises

a single molding" means "formed from a single mold." Markman Order at 13. The Ultrasite piston component is molded as a single piece, which satisfies the claim limitation. Therefore, the Court finds that the Ultrasite valve literally infringes claim 5 of the '673 patent.

5. Claim 6 of the '673 patent

Claim 6 of the '673 patent incorporates all the limitations in claim 1 and adds that the valve must further comprise of "a rigid member positioned within the flexible element and to assist in maintaining the flexible element along an axial centerline when the flexible element moves between the uncompressed position and the compressed position." The rigid plug in the Ultrasite valve satisfies this claim limitation. The rigid plug is made of a hard plastic, sits within the piston component, and prevents the piston assembly from bending when it is axially compressed. Braun contends that ICU undermines its infringement arguments regarding claim 1 because the piston component cannot be a "flexible element" if the rigid plug satisfies the "rigid member" limitation. This argument has already been rejected by the Court in its discussion of infringement of claim 1. Therefore, the Court finds that the unmodified Ultrasite valve literally infringes claim 6 of the '673 patent.

III. INFRINGEMENT OF THE '673 AND '204 PATENTS BY THE ULTRASITE VALVE WITH MODIFIED PISTON

The '673 patent requires, among other things, a medical valve comprising a "flexible element" having at least three "external diameters," with "at least a portion of the outer surface of the wall of the flexible element between the second diameter and the third diameter being tapered." Similarly, the '204 patent requires a "resilient seal element" having "at least two generally arcuate segments" with "at least one segment proximate to said bottom end having a larger maximum diameter than a second segment nearer to said top end of said element." The claim limitation requiring different-sized maximum diameters was added during prosecution of the '204 patent, and ICU has asserted that this created a "taper" limitation.

Braun does not refute the assertion that its unmodified Ultrasite valve contains a slight taper in the skirt of the piston component. Instead, it contends that the newly modified Ultrasite piston is straight-walled and cannot satisfy the "taper" limitation. In September and October of 2004, Braun modified the molds used to make the piston component to eliminate any mold draft. As a result, the modified piston component used in Ultrasite valves being manufactured today has straight walls. Braun has removed the alleged "taper" from the Ultrasite product, and now moves for summary judgment that the Ultrasite valve with modified piston does not infringe claims 1-6 of the '673 patent and claims 1-5 of the '204 patent.

A. Subject Matter Jurisdiction

Contrary to ICU's assertions, the Court has jurisdiction to decide Braun's summary judgment motion of non-infringement of the '673 and '204 patents by the Ultrasite valve with modified piston.

Under the Declaratory Judgment Act, a federal court may exercise jurisdiction over a matter only in "a case of actual controversy." 28 U.S.C. § 2201(a). The courts are forbidden from rendering advisory opinions. Arrowhead Indus. Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 735 (Fed. Cir. 1988). The test for determining whether an "actual controversy" exists involving patents is objective and two-pronged. First, an alleged infringer must have a reasonable apprehension that the patent holder will initiate suit if the party continues the allegedly infringing activity. Second, the alleged infringer must have either produced the device or have prepared to produce that device. Id. at 735-36.

Although subject matter jurisdiction is decided at the time of filing, once it has been established, a court may adjudicate all those claims and related defenses brought by the parties throughout the litigation as long as an "actual controversy" continues to exist. See Preiser v. Newkirk, 422 U.S. 395, 401 (1975) ("The rule in federal cases is that an actual controversy must be extant at all stages of review, not merely at the time the complaint was filed"). For this reason, plaintiffs do not need to file a new action on the

same patent for each modification made to an accused product during the course of litigation. Notably, the modified Ultrasite valve is not a new valve but a modification to one component of the same valve.

The Court has jurisdiction over the newly modified Braun Ultrasite valve. In its Complaint, ICU generically alleges that Braun is infringing the '673 and '204 patents "by making, using, offering for sale, and selling within the United States Braun's *Ultrasite needleless medical connectors*." First Amended Complaint at ¶ 7 (emphasis added). The newly-modified Ultrasite valve is essentially the same product ICU has accused of infringement in its Complaint, except the elastomeric piston component no longer has the non-functional mold draft that ICU alleges satisfies the "taper" limitation. In addition, ICU identifies in its Infringement Disclosures Braun's Ultrasite valve product family as "accused instrumentalities," including any future ones it may find in discovery: "ICU anticipates identifying additional infringing B.Braun Ultrasite Needle-Free Valve products after conducting discovery in this matter."[4] ICU's 3/31/04 Amended Initial Disclosure of Asserted Claims Under Patent L.R. 3-1.

Moreover, jurisdiction exists under Braun's declaratory counterclaim that its generic "Ultrasite needleless medical connectors" do not infringe the '673 patent. Braun's 3/5/04 Answer and Counterclaims at 12. An actual controversy existed at the time of filing because the parties were already in litigation over the Ultrasite valve product family, and Braun was making and selling the accused devices. See Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 96 (1993) ("If . . . a party has actually been charged with infringement of the patent, there is, *necessarily*, a case or controversy adequate to support jurisdiction of a complaint, or a counterclaim under the Act."). Braun's decision to modify the molds used to manufacture the piston component and

[4] Further, ICU seeks damages on sales during the litigation and an injunction against future sales. These remedies cannot be decided without first determining whether the Ultrasite valves with modified piston infringe the '673 and '204 patents, because Braun does not make any more Ultrasite valves with unmodified pistons for sale in the United States.

remove the alleged "taper" in the piston skirt did not divest the court of its jurisdiction over Ultrasite needleless medical connectors.

Jurisdiction over the newly modified Ultrasite valve also exists because Braun had a reasonable apprehension that ICU would initiate suit because it was already litigating the action and ICU had not stipulated to non-infringement by the Ultrasite valve with modified piston. The evidence also shows that all the molds used to make pistons for Ultrasite products for sale in the United States were changed by October 2004, and valves with modified pistons were being commercially sold and used by customers. Even if Braun had only switched the molds but was not yet selling the modified valve to customers, an actual controversy still exists because Braun had prepared to produce the Ultrasite valve with modified piston. See Int'l Med. Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc., 787 F.2d 572, 575 (Fed. Cir. 1986) ("[T]he statutory requirement is satisfied when . . . the plaintiff has 'actually produced the accused device' *or* has 'prepared to produce such a device.'") (emphasis added).

It is not necessary for ICU to make any allegations regarding the redesigned product in order for the Court to have jurisdiction over the Ultrasite valve with modified piston. Jurisdiction existed when ICU filed the infringement action against generic Ultrasite valves, and continues to the present day. There is no heightened pleading standard for identifying specific modifications for accused products in infringement actions. See Fed. R. Civ. P. 9 (specifying the claims and defenses that require pleading with particularity).

ICU's reliance on Laitram Corp. v. Cambridge Wire Cloth Co., 919 F.2d 1579 (Fed. Cir. 1990), is misplaced. Although the court in Laitram vacated summary judgment of non-infringement for lack of jurisdiction because the motion addressed products never accused of infringement, the facts are distinguishable from this case. There, the Federal Circuit was concerned with the *complete absence* of an accused product. Laitram, 919 F.2d at 1580 ("[T]he present record contains no evidence that any product accused of infringement had been made, used, or sold when the complaint was filed."). The only

products before the district court when it granted summary judgment were the non-accused "possible constructions" of the product. Id. at 1581. Consequently, the Federal Circuit held that there was no true case or controversy. Id. ("In its motion, [plaintiff] was effectively and improperly saying to the district court, 'if we make and sell any of these four "possible constructions" please advise that we won't infringe.' Federal Courts do not sit, however, to decide hypotheticals or to issue advisory opinions."). In contrast, the accused Braun Ultrasite valves with modified piston are being made, used, and sold. Moreover, the Ultrasite valve with modified piston was not merely a "possible construction" of the product. By the end of 2004, Braun had modified the molds used to produce the piston component for all the Ultrasite valves manufactured and sold in the United States.

ICU also relies on Field Container Co., L.P. v. Somerville Packaging Corp., 842 F. Supp. 338 (N.D. Ill. 1994). The facts in Field Container are also inapposite to this case. There, the court found that the plaintiff in a declaratory judgment action failed to satisfy the burden of demonstrating an actual controversy. Id. at 342-43. A letter threatening legal action sent to the plaintiff could not establish a reasonable apprehension of suit because it referenced an older version of the product that was "significantly different" from the version then being produced by the plaintiff. Id. at 342 ("We are therefore unwilling to apply the transitive property and convert any 'reasonable apprehension of suit' with respect to Version 1 to a 'reasonable apprehension of suit' with respect to Version 2."). Consequently, the court had no jurisdiction over the product at issue. In contrast, the difference between Braun's two Ultrasite valves is not substantial enough to bar a reasonable apprehension of suit with respect to the modified Ultrasite valve when ICU initiated its litigation against Braun's unmodified valve. Indeed, the two versions of the valve are almost identical. The mold draft on the piston component was a by-product of the manufacturing process, not a functional attribute of the product. Its removal did not alter the function or operation of the valve. Thus, it was reasonable for Braun to fear being sued for infringement if it manufactured the modified valve, particularly in light of

ICU's refusal to stipulate to non-infringement by the Ultrasite valve with modified piston. Braun satisfied its burden to demonstrate that an actual controversy exists, and the Court has jurisdiction to consider whether the Ultrasite valve with modified piston infringes the '673 and '204 patents.

B. Non-Infringement

The Court now turns to the merits of Braun's summary judgment motion with respect to the Ultrasite valve with modified piston. Both the '673 and '204 patents recite a medical valve containing a tapered structure. The parties agree that "tapered" means "to make gradually diminished in width toward one end." Braun's Opposition Memorandum at 21.

ICU asserts that the skirt of the piston component in Braun's Ultrasite valve satisfies this limitation. As to the Ultrasite valve with modified piston, Braun has now removed the alleged "taper" from the product. The piston skirt no longer gradually diminishes in width towards one end. Design drawings of the modified piston component show that the piston is no longer tapered. The piston skirt now consists of straight walls. Notably, even ICU does not contend that the modified Ultrasite product infringes (either literally or by virtue of the doctrine of equivalents) the '673 and '204 patents.

Thus, there is no genuine dispute that the modified Ultrasite valve does not infringe the '673 and '204 patents, and the Court grants Braun's motion for summary judgment of non-infringement by the Ultrasite valve with modified piston.

IV. INEQUITABLE CONDUCT

Braun has alleged in its pleadings that ICU's '673 patent is unenforceable because of the inequitable conduct of ICU during the prosecution of the '673 patent before the Patent and Trademark Office ("PTO").

Specifically, Braun argues that ICU committed inequitable conduct by failing to disclose the existence of this ongoing litigation and relevant litigation materials regarding infringement by the Ultrasite valve to the '673 patent examiner, while simultaneously

prosecuting a new patent application with a petition alleging infringement by the same Ultrasite valve.

The '673 patent application was filed as a continuation of an abandoned application originally filed in December 1991. The inventor, Dr. George Lopez,[5] successfully petitioned for an expedited examination of the application based on the alleged infringement of the new invention by Braun's Ultrasite valve. The petition did not disclose that the assignee of the '673 patent, ICU, had already been in litigation with Braun over the same Ultrasite valve for over a year. It also failed to inform the PTO that ICU alleged in the ongoing litigation that the same Ultrasite valve infringed the '204 patent—a patent that shares the same specification as the '673 patent.

ICU, however, contends that there is no evidence of inequitable conduct on its part as to the prosecution of the '673 patent. ICU points out that the PTO was notified by the Clerk of the United States District Court for the Northern District of California as to the pending litigation involving the '048 and '673 patents pursuant to 35 U.S.C. § 290. Moreover, ICU disclosed all relevant prior art, including every prior art patent raised during the course of litigation,[6] to the PTO during the '673 prosecution in accordance with the applicable regulations. ICU argues that there is no evidence of any intent on its part to deceive or mislead the PTO.

The Court finds that the existence of this ongoing litigation was material to the '673 patent prosecution, and that ICU failed to disclose this information to the '673 patent examiner. There is also sufficient evidence to raise a genuine issue of triable fact as to whether ICU failed to disclose this ongoing litigation with the intent to mislead or deceive

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[5] Dr. Lopez is also the inventor of the '204 patent and the Chief Executive Officer of plaintiff ICU Medical, Inc.

[6] The list of relevant prior art references raised during the course of litigation and disclosed by ICU to the PTO include: Armao (U.S. Patent No. 3,134,380), Adams (U.S. Patent No. 2,847,995), Vailancourt (U.S. Patent No. 4,512,766), DeFrank (U.S. Patent No. 5,242,432), Cambio (U.S. Patent No. 4,201,208), and Lopez (U.S. Patent No. 4,782,841).

the PTO. Consequently, summary judgment in favor of ICU with respect to Braun's affirmative defense of inequitable conduct as to the '673 patent is not appropriate.

A. Applicable Law

A patent applicant's duty to disclose material information to the PTO arises under the general duty of candor, good faith, and honesty as set forth in 37 C.F.R. § 1.56(a), which states, in part:

> Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.

37 C.F.R. § 1.56(a).

The Manual of Patent Examining Procedure ("MPEP") further provides:

> Where the *subject matter* for which a patent is being sought is or has been involved in litigation, *the existence of such litigation and any other material information arising therefrom* must be brought to the attention of the Patent and Trademark Office; such as, for example, evidence of possible prior public use or sales, questions of inventorship, prior art, allegations of 'fraud,' 'inequitable conduct,' or violation of duty of disclosure. Such information might arise during litigation in, for example, pleadings, admissions, discovery including interrrogatories, deposition, and other documents, and testimony.

MPEP § 2001.06(c) (emphasis added). Although MPEP § 2001.6(c) is not binding law, it sheds light on the PTO's official interpretation of 37 C.F.R. § 1.56(a) regarding the materiality of related litigation.

A patentee commits inequitable conduct if, "during prosecution of the application, he makes an affirmative representation of material fact, fails to disclose material information, or submits false material information, and does so with intent to deceive." Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1358 (Fed. Cir. 2003) (citation omitted). To find inequitable conduct, there must be clear and convincing evidence that both the materiality and intent prongs of the test are satisfied. See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1233 (Fed. Cir. 2003).

1. Sufficiency of § 290 Notice

ICU contends that the ongoing litigation relating to infringement by the Ultrasite valve was properly disclosed and brought to the attention of the PTO when the Clerk gave notice of this litigation pursuant to 35 U.S.C. § 290.[7]

The duties imposed by 37 C.F.R. § 1.56(a) and MPEP § 2001.06(c) cannot be supplanted by the general administrative notice required by Section 290. The patent applicant has an independent duty to disclose the existence of related patent infringement litigation to the PTO examiner. The duty of disclosure is particularly important in the context of patent prosecutions, which are conducted before an examiner in the absence of any represented adversary. In *ex parte* patent prosecutions, PTO examiners rely on the patent applicants to make full disclosure of material information of which they are aware in each case. See Amgen, Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp. 2d 69, 147 (D. Mass. 2001) ("[T]he duty of candor ultimately falls on the shoulders of the patent applicant . . . ."). Moreover, the PTO has hundreds of examiners who handle hundreds of thousands of applications annually, and one examiner is unlikely to be aware of the status or assertions that an applicant makes to another examiner.

Here, for example, although the Section 290 notice was sent to the PTO Director on the day the ongoing patent infringement action was filed, the PTO was directed under Section 290 to file the notice in the '204 and '048 patent file histories. Any Section 290 notice would not go to the examiner of the subsequent '673 patent application—a different, but related patent application. Indeed, the Section 290 notice appears nowhere in the '673 file history. As a result, the '673 patent examiner was unaware of this Court's

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[7] 35 U.S.C. § 290 provides:

> The clerks of the courts of the United States, within one month after the filing of an action under this title shall give notice thereof in writing to the Director, setting forth so far as known the names and addresses of the parties, name of the inventor, and the designating number of the patent upon which the action has been brought. . . . The Director shall, on receipt of such notices, enter the same in the file of such patent.

claim constructions on similar language from the '204 and '048 patents. The '673 patent examiner was never told about Braun's invalidity contentions. The '673 patent examiner was never shown *any* of the pleadings or documents in this litigation. Consequently, ICU cannot rely on Section 290 to satisfy its duty to disclose the existence of related litigation to the '673 patent examiner.

In fact, the PTO advises that "the individuals covered by 37 C.F.R. 1.56 cannot assume that the examiner of a particular application is necessarily aware of other applications which are 'material to patentability' of the application in question, but must instead bring such other applications to the attention of the examiner." MPEP § 2001.6(b).[8] Likewise, an applicant cannot assume that an examiner, however diligent and well-informed, will be aware of Section 290 notices in other patents. To do so would effectively eviscerate the duty of disclosure regarding related litigation owed to each patent examiner.

2. Materiality

Information must be disclosed to the PTO when it is material to patentability. Materiality is not limited to prior art but includes "any information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent. Bristol-Myers, 326 F.3d at 1234. According to the PTO, information is material to patentability if:

> It is not cumulative to information already of record [in the application], and
> (1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or
> (2) It refutes, or is inconsistent with, a position the applicant [has taken] in:
> (i) Opposing an argument of unpatentability relied on by the [PTO], or
> (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56(b).

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[8] Furthermore, applicants should "continue to submit information for consideration by the Office in applications rather than making and relying on their own determinations of materiality. An incentive remains to submit the information to the Office because it will result in a strengthened patent and will avoid later questions of materiality and intent to deceive." Critikon, 120 F.3d at 1257.

In fact, related litigation is material *per se*. See MPEP § 2001.06(c) (stating that "the existence of such litigation *and any other* material arising therefrom" is material); see also Daimlerchrysler AG v. Fueling Advanced Techs., Inc., 276 F. Supp 2d 1054, 1063 (S.D. Cal. 2003). Failure to disclose related litigation may lead to a finding of inequitable conduct. See Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1255-59 (Fed. Cir. 1997); Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 68 F. Supp. 2d 508, 550-51 (D.N.J. 1999) (denying patentee's preliminary-injunction motion because accused infringer had substantial defense of inequitable conduct based on patentee's failure to disclose materials from a related litigation to the examiner).

The materiality of the '204 and '048 patent litigation which challenged both the validity and enforceability of the subject matter of the '673 application is obvious. Indeed, even ICU does not dispute that this ongoing litigation was material to the '673 patent prosecution. ICU Brief at 5-6. The '204 patent shared the same specification and disclosed the same subject matter as the '673 application. Braun also raised invalidity contentions against the patents-in-suit and alleged inequitable conduct against ICU in connection with its prosecution of the '048 patent, which may have been material to patentability of the '673 application. See MPEP § 2001.6(c) ("Examples of []material information include . . . allegations of 'fraud,' 'inequitable conduct,' and 'violation of duty of disclosure.'").

3. Intent

As a general principle, the requirements of materiality and intent are inversely proportional. See Critikon, 120 F.3d at 1257. "A lesser quantum of intent is necessary when the omission or misrepresentation is highly material, and vice versa." Diamlerchrysler, 276 F. Supp. 2d at 1065 (quoting Amgen, 314 F.3d at 1358). Nevertheless, the intent to deceive or mislead cannot be inferred solely from the materiality of the omission. Amgen, 314 F.3d at 1358. Proof of intent to mislead may be shown by circumstantial evidence. Paragon Podiatry Lab., Inc. v. KLM Lab., Inc., 984

F.2d 1182, 1189-90 (Fed. Cir. 1993) ("'[S]moking gun' evidence is not required in order to establish an intent to deceive. . . . Rather, this element of inequitable conduct, must generally be inferred from the facts and circumstances surrounding the applicant's overall conduct.") (citation omitted).

A relatively high degree of intent may be demonstrated from the facts of this case. ICU was clearly aware that the subject matter of the pending litigation was material to the '673 patent prosecution. It knew that the claims of the '673 patent "read on" Braun's Ultrasite valve because it specifically alleged infringement by the Ultrasite valve in a Petition to Make Special to expedite examination of the '673 patent. Braun suggests that ICU's effort to obtain the '673 patent in time for use in this litigation provided a significant incentive for ICU to hide this litigation from the PTO examiner.[9]

During the prosecution of the '673 application, ICU also objected to Braun's motion to compel production of pending ICU patent applications that were related to the '204 patent. ICU repeatedly told Magistrate Judge James that the applications were not "relevant," despite having already filed a Petition to Make Special alleging infringement by the same Ultrasite valve. This made it impossible for Braun to inform the '673 patent examiner of the pending litigation.

Put another way, ICU may have been trying to hide the pending litigation from the '673 patent examiner while simultaneously using the alleged infringement by the Ultrasite

[9] Indeed, disclosing the ongoing litigation may have forced ICU to address their various positions during litigation and consequently delayed the '673 patent prosecution by raising relevant invalidity defenses and material prior art.

For example, the PTO examiner may have asked for more information regarding ICU's claim construction arguments that the '204 patent claims, which share the same specification as the '673 application, required a "taper" on the "resilient seal element" even if that term is never used. ICU relied on this "taper" limitation in opposing Braun's summary judgment motion for patent invalidity. Although the PTO examiner never had the opportunity to consider this information, ICU subsequently added an express "taper" limitation to the application claims of the '673 patent before it issued.

valve as a reason to expedite issuance of the '673 patent, which ICU could then use as a weapon in the ongoing litigation.

ICU's reliance on Haney v. Timesavers, Inc., 900 F. Supp. 1378, 1382 (D. Or. 1995) (stating that "the court cannot infer an intent to deceive . . . from the manner in which the information was conveyed to the Patent Office when the information was, in fact, conveyed.") is misplaced. In Haney, the district court found insufficient evidence to infer an intent to deceive and sustain an inequitable conduct claim. Id. Here, however, there is substantial evidence from which the Court could find that ICU had the intent to deceive the PTO regarding ongoing litigation surrounding the Ultrasite valve. ICU's failure to disclose the existence of this ongoing litigation regarding infringement by the Ultrasite valve to the '673 patent examiner, as well as the existence of the '673 application during discovery, while simultaneously prosecuting a new patent application with a petition alleging infringement by the same valve, raises a genuine issue of triable fact as to inequitable conduct.

CONCLUSION

For the reasons stated above, the Court hereby resolves the motions as follows:

1. ICU's motion for summary judgment that Braun's Ultrasite valve infringes the '673 patent is GRANTED in part as to claims 1-2 and 5-6, and DENIED in part as to claim 3.
2. Braun's motion for summary judgment that the Ultrasite valve does not infringe the '673 patent is DENIED in part as to claims 1-2 and 4-6, and GRANTED in part as to claim 3.
3. Braun's motion for summary judgment that the Ultrasite valve with modified piston does not infringe the '673 and '204 patents is GRANTED.
4. ICU's motion for summary judgment of no inequitable conduct is DENIED.

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It is further ORDERED that trial on the issue of inequitable conduct shall begin on April 11, 2005 at 8:30 a.m. A pretrial conference shall be held on March 31, 2005 at 2:30 p.m.

IT IS SO ORDERED.

Dated: March 14, 2005

/s/
CHARLES R. BREYER
UNITED STATES DISTRICT JUDGE

EXHIBIT G

LegalMetric®

LegalMetric District Judge Report

Central District of California

Patent Cases

January, 1991 to April, 2007

The information contained in this report is obtained from the official docket records of the federal courts. No attempt has been made to correct that data. For example, cases may be misclassified in the official docket records. In addition, cases are classified only by the primary cause of action. Cases having multiple causes of action are analyzed only under the primary cause of action identified on the official court docket.

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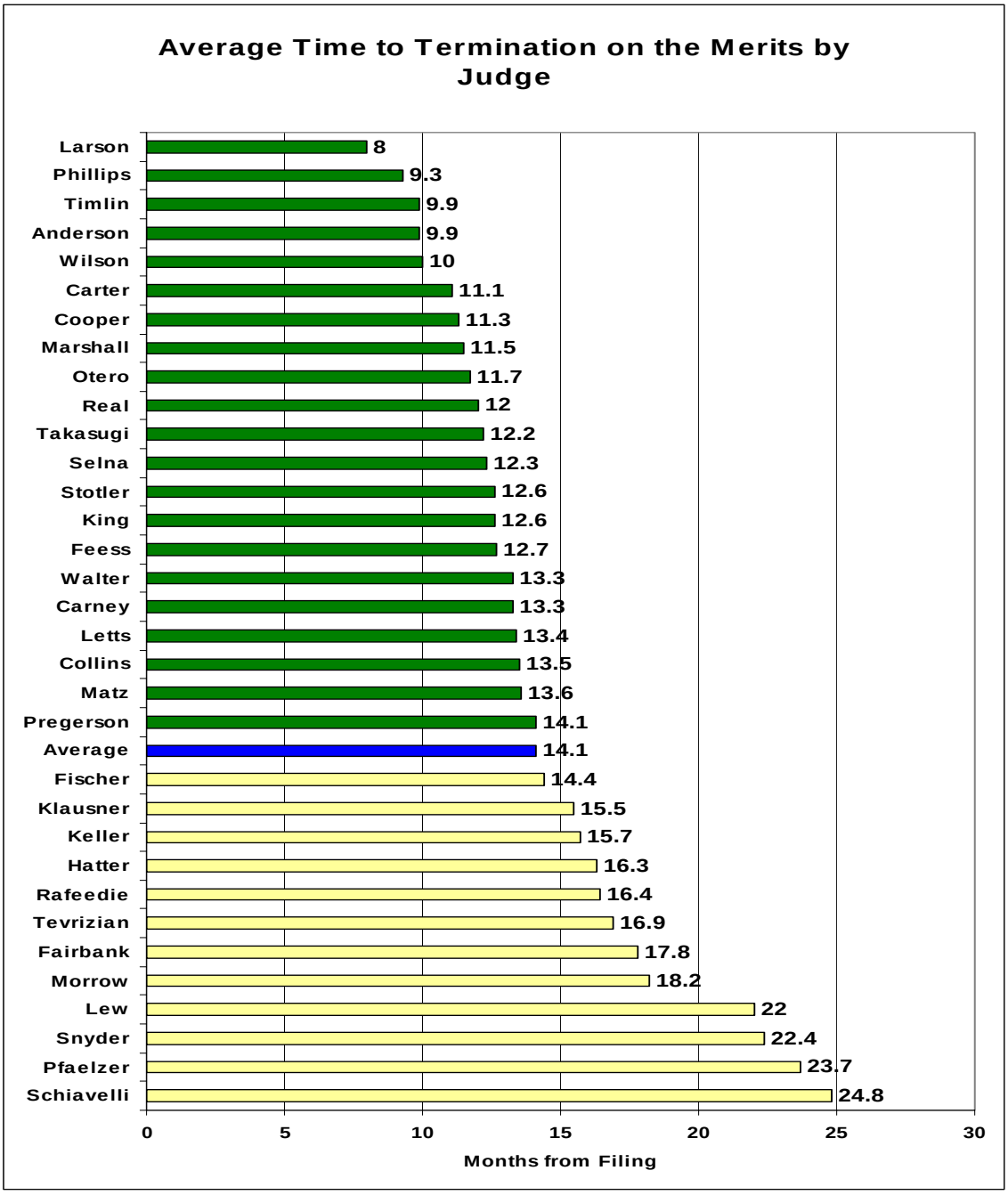
Average Pendency for All Terminations on the Merits—By Active Judge

The average time from filing to termination on the merits in these cases was 14.1 months. There is considerable variation of average pendency by judge, ranging from 8.0 months for Judge Larson to 24.8 months for Judge Schiavelli. The chart below shows the variation for average time to termination on the merits by judge.



Average Pendency for Bench Trials—By Active Judge

The average time from filing to termination by bench trial was 42.4 months. For those judges who had at least one patent case with a bench trial during this period, the average time from filing until termination by bench trial varied from 11.8 months for Judge Stotler to 126.4 months for Judge Matz.

Judge	Number of Bench Trials	Average Time from Filing to Termination by Bench Trial (Months)
Average for the Court	0.3	42.4
Feess	1	47.5
Hatter	1	30.6
Lew	2	30.6
Marshall	1	38.6
Matz	1	126.4
Pfaelzer	2	21.4
Real	1	65.5
Stotler	1	11.8

Average Pendency for Jury Trials—By Active Judge

The average time from filing to termination of patent cases by jury verdict in the Central District of California was 32.7 months. By judge, average time to termination for jury verdicts ranged from 14.4 months for Judge Keller to 91.4 months for Judge Schiavelli. The chart below illustrates the variation among judges.

Judge	Number of Jury Trials	Average Time from Filing to Termination by Jury Trial (Months)
Average for the Court	0.9	32.7
Carney	1	63.4
Carter	3	32.1
Collins	1	80.3
Keller	3	14.4
Klausner	2	28.6
Letts	1	19.8
Lew	1	43.1
Pfaelzer	3	40.6
Pregerson	2	33.3
Rafeedie	6	16.8
Real	1	27.5
Schiavelli	1	91.4
Snyder	1	41.6
Stotler	1	69.4
Tevrizian	1	21.3
Wilson	2	19.5

Average Pendency for Cases Terminated by Summary Judgment—By Active Judge

The average time from filing to termination by summary judgment in patent cases in the Central District of California was 19.9 months. By judge, average time to termination for summary judgments ranged from 11.5 months for Judge Collins to 38.6 months for Judge Hatter. The table below illustrates the variation among judges.

Judge	Number of Terminations by Summary Judgment	Average Time from Filing to Termination by Summary Judgment (Months)
Average for the Court	3.8	19.9
Carney	6	14.2
Carter	9	13.2
Collins	2	11.5
Cooper	3	16.3
Feess	3	13.8
Hatter	2	38.6
Keller	2	20.5
King	1	29.8
Klausner	4	17.2
Letts	2	34.0
Lew	7	29.4
Marshall	2	15.5
Matz	3	20.2
Morrow	1	23.6
Otero	5	16.3
Pfaelzer	12	28.5
Pregerson	4	15.9
Rafeedie	7	13.9
Real	12	15.7
Schiavelli	2	21.4
Selna	9	17.0
Snyder	5	23.5
Stotler	11	19.5
Tevrizian	7	29.3
Timlin	2	25.3
Walter	1	13.8
Wilson	9	17.8

EXHIBIT H

LegalMetric®

LegalMetric District Judge Report

District of Delaware

Patent Cases

February, 2006

The information contained in this report is obtained from the official docket records of the federal courts. No attempt has been made to correct that data. For example, cases may be misclassified in the official docket records. In addition, cases are classified only by the primary cause of action. Cases having multiple causes of action are analyzed only under the primary cause of action identified on the official court docket.

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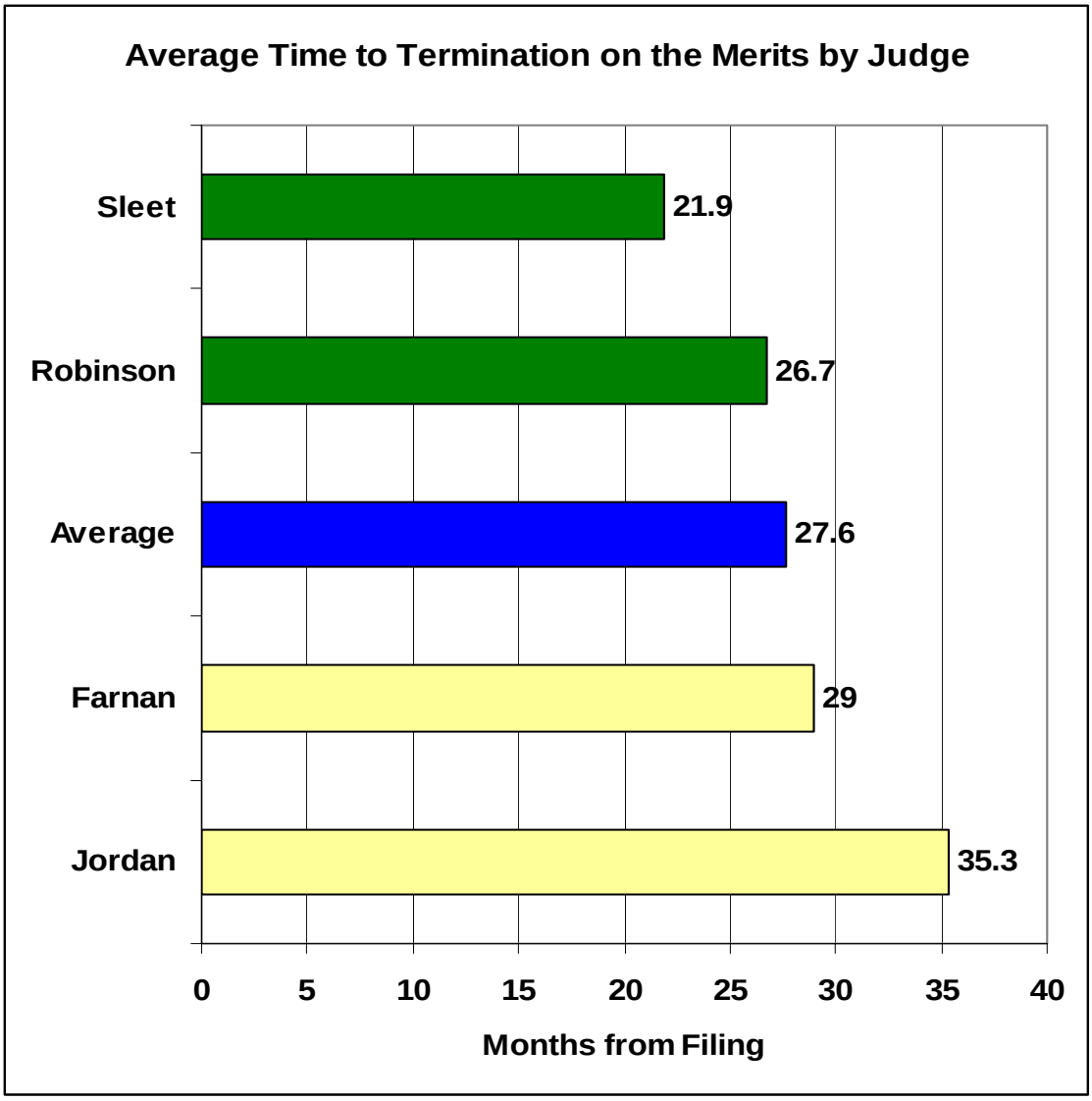
Average Pendency for All Terminations on the Merits—By Judge

The average time from filing to termination on the merits in these cases was 27.6 months. There is considerable variation of average pendency by judge, ranging from 21.9 months for Judge Sleet to 35.3 months for Judge Jordan. The chart below shows the variation for average time to termination on the merits by judge.



Average Pendency for Bench Trials—By Judge

The average time from filing to termination by bench trial was 44.4 months. For those judges who had at least one patent case with a bench trial during this period, the average time from filing until termination by bench trial varied from 19.7 months for Judge Jordan to 52.7 months for Judge Farnan.

Judge	Number of Bench Trials	Average Time from Filing to Termination by Bench Trial (Months)
Average for the Court	7.8	44.4
Farnan	16	52.7
Jordan	2	19.7
Robinson	12	38.8
Sleet	1	29.0

Average Pendency for Jury Trials—By Judge

The average time from filing to termination of patent cases by jury verdict in the District of Delaware was 31.8 months. By judge, average time to termination for jury verdicts ranged from 23.3 months for Judge Sleet to 38.8 months for Judge Robinson. The chart below illustrates the variation among judges.

Judge	Number of Jury Trials	Average Time from Filing to Termination by Jury Trial (Months)
Average for the Court	11.2	31.8
Farnan	22	28.2
Jordan	3	37.6
Robinson	15	38.8
Sleet	5	23.3

Average Pendency for Cases Terminated by Summary Judgment—By Judge

The average time from filing to termination by summary judgment in patent cases in the District of Delaware was 31.0 months. By judge, average time to termination for summary judgments ranged from 25.3 months for Judge Robinson to 36.5 months for Judge Jordan. The table below illustrates the variation among judges.

Judge	Number of Terminations by Summary Judgment	Average Time from Filing to Termination by Summary Judgment (Months)
Average for the Court	6.0	31.0
Farnan	5	32.4
Jordan	6	36.5
Robinson	7	25.3
Sleet	6	30.9

Average Pendency for Cases Terminated by Transfer—By Judge

The average time from filing to termination by transfer in patent cases in the District of Delaware was 5.7 months. By judge, average time to termination for transfers ranged from 3.0 months for Judge Jordan to 9.4 months for Judge Robinson. The table below illustrates the variation among judges.

Judge	Cases Transferred	Average Time from Filing to Transfer (Months)
Average for the Court	15.0	5.7
Farnan	17	7.3
Jordan	7	3.0
Robinson	23	9.4
Sleet	22	4.8